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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/423,259    03/02/00    HANNI    C    97- MA- CNR-

000466    HM22/1106  
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EXAMINER

EINSMANN, J

ART UNIT	PAPER NUMBER
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1655

*13*

DATE MAILED:

11/06/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/423,259

Applicant(s)

HANNI ET AL.

Examiner

Juliet C. Einsmann

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-3, 10-12 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-9 and 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☒ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_.

Art Unit: 1655

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of Group II, claims 4-9 and 13-15 in Paper No. 12 is acknowledged.

### ***Claim Objections***

2. Claim 13 is objected to because it depends from a non-elected claim.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 4, 5, 7, 8, 9, 14, and 15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are broadly drawn to comprise polynucleotides with at least 80%, preferably 90% and advantageously 95% identity to specific sequences. The essential feature of this invention is unclear (See Written Description guidelines, 64 Fed Reg 71427). The essential feature appears to be the ability to detect mitochondrial DNA of bovine species in a sample, however, this claim broadly claims any polynucleotides with as little as 80% identity to the specifically disclosed species. The specification does not provide guidance as to where to make these changes while still maintaining the selectivity of the polynucleotides. The claim as written reads on many polynucleotides as yet not described, including, for example, genes and disease

Art Unit: 1655

markers. Therefore, the instant disclosure of a these specific sequences (which each represent a single species) is not sufficient to provide written description for the broadly claimed genus in light of the ambiguity of the claim and the absence of functional language to further define the variants.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 4-9 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 5, 7, 14, and 15 are indefinite over the use of the phrase “in particular” because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 4, 5, 6, 14, and 15 are indefinite over the recitation of the phrase “are made up of” because it is unclear what limitation this phrase places on the claim, that is, it is unclear if applicant intends for this to be open or closed claim language.

Claim 6 is indefinite over the recitation of the term “made up of” because it is not clear if this is meant to be open or closed claim language. That is, it is unclear if the primer pair is intended to “consist of” primers selected from the recited sequences or if the primer pair is intended to simply comprise the recited sequences.

Claims 8 and 9 are indefinite over the recitation of “a minimum of about 15” and “a minimum of about 20,” because, for example, it is not clear if 15 is intended to be the minimum or if there is allowed a minimum below 15 nucleotides.

Art Unit: 1655

Claim 13 is indefinite over the recitation of “about 500 about 100” base pairs because this language is unclear.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 4, 5, 8, 9, 13, 14, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Loftus *et al.* (PNAS USA Vol. 91, pp. 2757-2761, March 1994).

Loftus *et al.* teach oligonucleotides which comprise mtDNA from representative breeds of cattle. Loftus *et al.* teach many different sequences which are fully disclosed as GenBank accession numbers L27712-L7737 (p. 2757). These sequences comprise the instantly claimed sequences.

For example, instant SEQ ID NO: 1 consists of the reverse complement of nucleotides 670-712 of the sequence disclosed in GenBank Accession number L27725 (see attached GenBank record). Instant SEQ ID NO: 2 and 3 are therefore also within this sequence taught by Loftus *et al.* since they are merely segments of instant SEQ ID NO: 1.

Instant SEQ ID NO: 4 consists of nucleotides 211-256 of the sequence disclosed in GenBank Accession number L27725. Instant SEQ ID NO: 5 and 6 are therefore also within this sequence taught by Loftus *et al.* since they are merely segments of instant SEQ ID NO: 4.

Instant SEQ ID NO: 8 consists of nucleotides 225-705 of the sequence disclosed in GenBank Accession number L27725. Therefore, this sequence taught by Loftus *et al.* also

Art Unit: 1655

comprises instant SEQ ID NO: 7 (nucleotides 310-336) and 19 (nucleotides 423-447), which are merely segments of SEQ ID NO: 8.

Instant SEQ ID NO: 15 consists of nucleotides ~~15824-15981~~<sup>10-1877</sup> of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 16 consists of nucleotides 225-337 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 17 consists of nucleotides 441-705 of the sequence disclosed in GenBank Accession number L27725.

Instant SEQ ID NO: 18 consists of nucleotides 745-902 of the sequence disclosed in GenBank Accession number L27712 (see attached GenBank record).

The teachings of Loftus *et al.* comprise all of the instantly claimed sequences. With respect to claim 13, each of the DNA fragments taught by Loftus *et al.* are considered to meet the limitations of claim 13 since they were all amplified by PCR (p. 2757) and certainly all comprise a sequence of 500 OR 100 base pairs.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Loftus *et al.* (PNAS USA, Vol. 91, pp. 2757-2761, March 1994) in view of Fei *et al.* (Animal Science and Technology (1996) Vol. 67, No. 10, pp. 900-905).

Loftus *et al.* teach the sequences of the D loops of the mtDNA from a number of cattle breeds. These sequences are fully disclosed in GenBank accession numbers L27712-27737. Instant SEQ ID NO: 1 consists of the reverse complement of nucleotides 670-712 of the sequence disclosed in GenBank Accession number L27725 (see attached GenBank record). Instant SEQ ID NO: 2 and 3 are therefore also within this sequence taught by Loftus *et al.* since they are merely segments of instant SEQ ID NO: 1. Instant SEQ ID NO: 4 consists of nucleotides 211-256 of the sequence disclosed in GenBank Accession number L27725. Instant SEQ ID NO: 5 and 6 are therefore also within this sequence taught by Loftus *et al.* since they are merely segments of instant SEQ ID NO: 4.

Furthermore, the sequence taught by Loftus *et al.* and fully disclosed in GenBank accession number L27725 also comprises instant SEQ ID NO: 9-14. Instant SEQ ID NO: 9 consists of nucleotides 19-43, instant SEQ ID NO: 10 consists of the reverse complement of nucleotides 158-177, instant SEQ ID NO: 11 consists of the reverse complement of nucleotides 358-377, instant SEQ ID NO: 12 consists of nucleotides 441-60, instant SEQ ID NO: 13 consists of nucleotides 715-734, and instant SEQ ID NO: 14 consists of the reverse complement of nucleotides 854-873.

Loftus *et al.* do not teach primer pairs which comprise oligonucleotides that consist of the instantly disclosed sequences.

Fei *et al.* teach methods for specific identification of meat from cattle using the PCR with primers designed to amplify portions of the mitochondrial D-loop DNA sequence (p. 900-905). Primer BF taught by Fei *et al.* consists of nucleotides 397-416 of the sequence taught by Loftus *et al.* The primer taught by Fei *et al.* is considered to be a functional homologue of all of the

Art Unit: 1655

primers of the instantly claimed invention, since the primer disclosed by Fei *et al.* possesses the same function as those of the instant invention, namely to amplify portions of the D loop mtDNA from cattle.

In light of the sequences taught by Loftus *et al.* and the teaching by Fei *et al.* that beef samples can be specifically identified by PCR amplification of the D-loop of mitochondrial DNA, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have selected any primers from the sequences taught by Loftus *et al.* in order to have provided functional homologues of the primers taught by Fei *et al.* The selection of different primer pairs from the sequences taught by Loftus *et al.* would have provided the ordinary practitioner with additional mechanisms for the specific detection of beef products in meat samples. The ordinary practitioner would have had a more than reasonable expectation of success since Fei *et al.* teach that amplification with primers specific for the D-loop mtDNA of cattle results in the ability to detect small amounts of beef in a mixed meat sample, for example 0.1% of beef in pork.



Art Unit: 1655

*Conclusion*

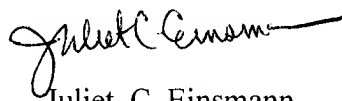
11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
JEFFREY FREDMAN  
PRIMARY EXAMINER

  
Juliet C. Einsmann  
Examiner  
Art Unit 1655

November 2, 2000